Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Stiefel Dry Skin Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Arachis Oil 21.0 % w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream
A white homogeneous oil-in-water cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

To reduce moisture loss from the epidermis and restore resilience to and protection against external factors in the treatment of dry, sensitive skin, lanolin sensitivity, alkali intolerance, ichthyosis and similar conditions.

4.2 Posology and method of administration

Stiefel Dry Skin Cream may be used as often as required. Apply to the affected areas and rub in well.

It is especially effective after washing when the normal acid condition of the skin may be disturbed and when the sebum content of the stratum corneum may be depleted.

4.3 Contraindications

Known hypersensitivity to the ingredients.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

There is no restriction on the use of the product during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Arachis Oil exerts an emollient effect by forming an occlusive film which reduces trans-epidermal water loss, thus restoring normal skin humidity levels.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone
Propylene Glycol
Glycerol Monostearate
Macrogol Monostearate
Stearic Acid
Isopropyl Palmitate
Dowicil 200
Potassium Sorbate
Essence 2174 H
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Internally lined aluminium tubes of 40g and 80g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Stiefel Laboratories (UK) Ltd
Holtspur Lane
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HP10 0AU
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8 MARKETING AUTHORISATION NUMBER

PA 144/23/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 01 October 1984

Date of last renewal: 01 October 2004

10 DATE OF REVISION OF THE TEXT

June 2006